

REMARKS

Claims 31 and 33 – 36 are pending in this application.

Claims 31 and 33 – 36 have been rejected.

Claims 31, 33 and 35 are currently amended.

Amendments to the Drawings

Figures 1 – 7 have been amended to provide electronically drafted versions of the previously submitted figures. These amendments are supported in Figures 1 – 7 as originally filed. Figure 7 has been amended to clarify the figure by explicitly providing vertical scales for all three of the measurements that are taken (1/Impedance, Cardiac Output and Congestion) relative to the horizontal scale. These amendments are supported in Figure 7 as originally filed and at page 16, lines 3 – 12 and throughout the specification. No new matter has been added.

Amendments to the Claims

Claim 31 has been amended to clarify the claim by deleting “at the locality where the impedance measurements are to be performed” and to correct an error in antecedent basis. No new matter has been added.

Claim 33 has been amended to change “identifying congestive heart failure” to “evaluating congestive heart failure” in lines 1 and 12. This amendment is supported at page 6, lines 17 – 23, which recites “...for performing said evaluation, and evaluation apparatus for evaluating the trend of the heart rate/activity pattern and the impedance against one another, over a selected period of time.” The amendment to claim 33 is further supported throughout the specification. No new matter has been added.

Claim 35 has been amended in view of the amendment to claim 33. No new matter has been added.

Objections to the Drawings

Figures 2 – 4 have been objected to for not having the appropriately sized lettering. Figures 2 – 4 have been amended to provide appropriately sized lettering, among other clarifications. Thus, it is respectfully submitted that the grounds for the objections to Figures 2 – 4 have been cured and that the objections to Figures 2 – 4 should be withdrawn.

Figures 6 and 7 have been objected to for containing illegible writing. Figures 6 and 7 have been amended to provide legible, computer-generated writing. Thus, it is respectfully submitted that the grounds for the objections to Figures 6 and 7 have been cured and that the objections to Figures 6 and 7 should be withdrawn.

Objections to the Claims

Claim 31 has been objected to because of informalities. It is noted that claim 31 has been amended to delete the subject matter “at the locality where the impedance measurements are to be performed” and to change “the trend” to “a trend”. Thus, it is respectfully submitted that the grounds for the objection to claim 31 have been cured and that the objection to claim 31 should be withdrawn.

Rejections Under 35 U.S.C. § 112

Claims 33 – 36 have been rejected under 35 USC § 112, first paragraph, as failing to comply with the written description requirement. These rejections are respectfully traversed.

Claim 33 has been rejected for reciting identifying congestive heart failure. It is noted, as described above, that claim 33 has been amended to recite “evaluating congestive heart failure.” As the Office Action notes, evaluating congestive heart failure is supported in the specification (Office Action, page 3, paragraph 5, lines 7 – 10). Thus, it is respectfully submitted that grounds for the rejection of claim 33 have been cured, and that the rejection of claim 33 under 35 USC § 112, first paragraph, should be withdrawn.

Claims 34 – 36 depend from claim 33 and as such incorporate all of the subject matter of claim 33. Because the ground for rejection of claim 33 has been cured, and because of the additional patentable subject matter, it is respectfully submitted that the grounds for rejection of claims 34 – 36 have similarly been cured, and that the rejections of claims 34 – 36 under 35 USC § 112, first paragraph, should be withdrawn.

Rejections Under 35 U.S.C. § 102

Riff '353

Claims 31 – 36 have been rejected under 35 USC § 102(b) as being anticipated by U.S. Patent No. 5,876,353 ("Riff '353"). It is noted that claim 32 has been previously canceled, rendering the rejection of claim 32 moot. The rejections of the claims, as amended, are respectfully traversed.

Riff '353 discloses an impedance monitor for discerning edema through evaluation of a respiratory rate. Surface mounted electrodes sense "edema measurement signal values" by measuring voltage or impedance of the tissue between electrode pairs (column 4, line 53 – column 5, line 2). As such, Riff '353 specifically discloses conducting edema measurements and does not show, disclose or suggest means for determining congestive heart failure on the basis of factors other than the existence of edema. In addition, Riff '353 does not show, disclose or suggest detecting the patient's heart rate/activity pattern and evaluating the trend of the heart rate/activity pattern and lung impedance measurements against one another over a selected period of time as an indicia of congestive heart failure.

By contrast, claim 31 recites early detection and monitoring of congestive heart failure, measuring impedance of a portion of a patient's body generally occupied by the lungs solely through surface mounted electrodes in a subcutaneously implanted device, and determining when the local impedance measurements are indicative of a condition of congestive heart failure based on factors other than the existence of edema. Claim 31 further recites detecting the patient's heart rate/activity pattern through the surface mounted electrodes of the subcutaneously implanted device, and evaluating a trend of

heart rate/activity pattern and concurrent local impedance measurements against one another as an additional indicia of congestive heart failure. Claim 33 recites measuring an impedance value of the lungs and the vicinity of the lungs solely through surface-mounted electrodes, detecting a characteristic of the heart with the surface-mounted electrodes, determining a trend based on the impedance value and the characteristic of the heart, and evaluating congestive heart failure as a function of the impedance value and the trend.

Riff '353 does not show, disclose or suggest multiple elements of claims 31 and 33. Riff '353 does not show, disclose or suggest surface-mounted electrodes on a subcutaneous device that both measure local impedance and detect the patient's heart rate/activity pattern. The creation of a subcutaneous device with surface-mounted electrodes that performs both of these functions is not a simple concept, and a device that simply suggests taking transthoracic impedance measurements from surface-mounted electrodes does not inherently disclose surface-mounted electrodes that both takes local impedance measurements and detects heart rate/activity patterns.

Further, Riff '353 does not show, disclose or suggest evaluating a trend of heart rate/activity patterns and local impedance against one another as an indication of congestive heart failure. Nor does Riff '353 disclose taking two different factors, such as local impedance and heart rate/activity patterns, to lend any insight at all into congestive heart failure.

For at least these reasons, Riff '353 does not show, disclose or suggest multiple elements of claim 31. Thus, it is respectfully submitted that the rejection of claim 31 under 35 USC § 102(b) as being anticipated by Riff '353 is improper and should be withdrawn.

Combs et al '861

Claims 31 – 36 have been rejected under 35 USC § 102(b) as being anticipated by U.S. Patent No. 5,957,861 ("Combs et al '861"). It is noted that claim 32 has been

previously canceled, rendering the rejection of claim 32 moot. The rejections of the claims, as amended, are respectfully traversed.

Combs et al '861 discloses an impedance monitor for discerning edema through evaluation of a respiratory rate. Surface mounted electrodes sense “edema measurement signal values” by measuring voltage or impedance of the tissue between electrode pairs (column 4, line 53 – column 5, line 2). The electrode pairs measure various impedance values, but Combs et al '861 specifically discloses conducting edema measurements and does not show, disclose or suggest means for determining congestive heart failure on the basis of factors other than the existence of edema. In addition, Combs et al '861 does not show, disclose or suggest detecting the patient’s heart rate/activity pattern and evaluating the trend of the heart rate/activity pattern and lung impedance measurements against one another over a selected period of time as an indicia of congestive heart failure.

By contrast, claim 31 recites early detection and monitoring of congestive heart failure, measuring impedance of a portion of a patient’s body generally occupied by the lungs solely through surface mounted electrodes in a subcutaneously implanted device, and determining when the local impedance measurements are indicative of a condition of congestive heart failure based on factors other than the existence of edema. Claim 31 further recites detecting the patient’s heart rate/activity pattern through the surface mounted electrodes of the subcutaneously implanted device, and evaluating a trend of heart rate/activity pattern and concurrent local impedance measurements against one another as an additional indicia of congestive heart failure. Claim 33 recites measuring an impedance value of the lungs and the vicinity of the lungs solely through surface-mounted electrodes, detecting a characteristic of the heart with the surface-mounted electrodes, determining a trend based on the impedance value and the characteristic of the heart, and evaluating congestive heart failure as a function of the impedance value and the trend.

Combs et al '861 does not show, disclose or suggest multiple elements of claims 31 and 33. Combs et al '861 does not show, disclose or suggest surface-mounted electrodes on a subcutaneous device that both measure local impedance and detect the

patient's heart rate/activity pattern. The creation of a subcutaneous device with surface-mounted electrodes that performs both of these functions is not a simple concept, and a device that simply suggests taking transthoracic impedance measurements from surface-mounted electrodes does not inherently disclose surface-mounted electrodes that both takes local impedance measurements and detects heart rate/activity patterns.

Further, Combs et al '861 does not show, disclose or suggest evaluating a trend of heart rate/activity patterns and local impedance against one another as an additional indication of congestive heart failure. Nor does Combs et al '861 disclose taking two different factors, such as local impedance and heart rate/activity patterns, to lend any insight at all into congestive heart failure.

For at least these reasons, Combs et al '861 does not show, disclose or suggest multiple elements of claim 31. Thus, it is respectfully submitted that the rejection of claim 31 under 35 USC § 102(b) as being anticipated by Combs et al '861 is improper and should be withdrawn.

Summary

In view of the amendments and arguments presented, claims 31 and 33 – 36 should be allowable. This application should be in condition for allowance and a notice to that effect is earnestly solicited.

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